

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/183,375	10/30/98	SZEBENI	J 003/098/SAP

HM12/1010

THOMAS G. WISEMAN
VENABLE, BAETJER, HOWARD & CIVILETTI LL
SUITE 1000
1201 NEW YORK AVENUE, N. W.
WASHINGTON DC 20005

EXAMINER

KISHORE, G

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/183,375

Applicant(s)

Alving

Examiner

Rishore
First-Last

Art Unit

1234
1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 7-9, 11, 18, and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10, and 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: :1615

DETAILED ACTION

The request for the extension of time and filing under 1.53 (d) continuation dated 7-31-01 are acknowledged.

Claims included in the prosecution are 1-6, 10 and 12-17. Applicant's intent to cancel claims 12-13 and 15 is noted. However, since applicant did not indicate the cancellation of said claims in the amendment section, they have not been canceled. The examiner suggests cancellation of these claims in their response.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is being conveyed by 'multivitamin product' in claim 1. The claim recites 'active ingredient' in singular and multivitamin product is a combination of active ingredients. Furthermore, it is unclear from the claims which of the active ingredients cause the hypersensitivity.

Art Unit: :1615

Claims 10 and 14 are inconsistent with claim 1. According to claim 1, the components are administered in conjunction and the claim 1 recites specific amphiphilic carriers.

What is being conveyed by ‘emulsifiers or detergent molecules’ in claim 2? First of all, polyethoxylated oil itself is an emulsifier; secondly, applicant also recites ‘derivatives’ separately and that term includes even emulsifiers. Applicant’s amendment deleting just ‘thereof’ does not fully address the issue because as pointed out before, the specific compound recited itself comes under the category of an emulsifier and detergent. This rejection is maintained since applicant has not addressed this issue.

The distinction between cremophor and cremophor EL as recited in claim 4 is unclear. Chemical names should be recited. The use of Trade names is improper.

What is meant by ‘particulate biomaterials’ which is recited as carrier in claim 14; claim 1 recites specific amphiphilic compounds and though the term as such is an art recognized word, its meaning in this context is unclear. What is the distinction between the emulsifiers in this claim and that in claim 2?

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the

Art Unit: :1615

prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156).

Ko discloses a method of inhibiting complement activation by administering complement activation inhibitors. The method involves the administration of the inhibitor in controlled release delivery devices such as liposomes. The method is used for various conditions including the drug induced allergies and inflammation (note the abstract, col. 3, lines 49-52, col. 5, lines 32-51, col. 11, lines 1-42, examples and claims). Although Ko does not specifically teach the administration of the inhibitor together with the drug, it would have been obvious to one of ordinary skill in the art to administer together since Ko is suggestive of this combination from his statements on col. 10, line 42 et seq., according to which the inhibitor "can be combined with appropriate pharmaceutical formulation. An artisan would be motivated further to administer the drug or an agent which causes the side effects along with the inhibitor since the reference of De Lacharriere teaches such a concept; according to De Lacharriere hydroxy acids which cause side effects and the substance P antagonist which prevent these side effects are administered together. The criticality of cremophor (an amphiphilic compound) is unclear in the absence of unexpected results.

Art Unit: :1615

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Ko teaches chimeric molecules which inhibit complement activation and these proteins are taught to reduce the inflammation and that the conditions mentioned include those associated with ischemia-reperfusion, crash injury etc. Applicant is incorrect; Ko in Table I on col. 11 teaches drug allergy and this comes under the term, 'hypersensitivity'. As pointed out in the previous action, the prior art of Obrien (Annals of Oncology, 1992) submitted by applicant himself classifies drug allergy as 'hypersensitivity'. Applicant's arguments with regard to the differences in latency periods are not found to be persuasive since that is not a requirement in the instant claims. With regard to applicant's arguments that De Lacharriere does not teach hypersensitivity associated with complement activation by amphiphilic molecules, the examiner points out that instant claims do not clearly recite that the amphiphilic molecule is responsible for the side effects. The claims as recited read on entire composition causing the side effects. Even assuming that the side effects are only due to the amphiphilic molecule, De Lacharriere is combined to show that administration of compositions causing side effects together with those which reduce the side effects is routinely practiced in the art.

5. Claims 1-6, 10 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ko (5,851,528) by itself or in combination with De Lacharriere (5,744,156), in further combination with applicant's statements of prior art.

Art Unit: :1615

Neither Ko nor De Lacharriere teach the use of cremophor as a drug or as a carrier. The references do not also teach that cremophors or liposomes cause compliment activation. Applicant on pages 5 and 6 cite various references which show that cremophors and liposomes cause compliment activation. Since the reference of Ko teaches that the inhibitors of complement activation for the treatment of conditions resulting from complement activation, it would have been obvious to one of ordinary skill in the art to use Ko's inhibitors for cremophor induced side effects since one would expect similar results irrespective of what causes the complement activation.

This rejection is maintained since applicant provides no specific arguments.

Art Unit: :1615

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Application/Control Number: 09/183,375

Page 8

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 9, 2001